



Practitioner's Docket No. MPI02-202P1RNM

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:	George Mulligan et al.		
Application No.:	10/728,055	Group No.:	1642
Filed:	December 4, 2003	Examiner:	Reddig, Peter J.
For:	METHODS FOR THE IDENTIFICATION, ASSESSMENT, PREVENTION AND TREATMENT OF PATIENTS WITH PROTEASOME INHIBITION THERAPY		

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT

**IDENTIFICATION OF TIME OF FILING THE ACCOMPANYING
INFORMATION DISCLOSURE STATEMENT**

The information disclosure statement submitted herewith is being filed:

- ☒ Within three months of the filing date of the application or date of entry into the national stage of an international application or before the mailing date of a first Office action on the merits, whichever event occurs last. 37 C.F.R. section 1.97(b).

OR

- ☐ *After* three months of the filing date of this national application or the date of entry of the national stage as set forth in Section 1.491 in an international application or after the mailing date of the first Office action on the merits, whichever event occurred last but *before* the mailing date of either:

CERTIFICATION UNDER 37 C.F.R. SECTIONS 1.8(a) and 1.10*

I hereby certify that, on the date shown below, this correspondence is being:

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37 C.F.R. SECTION 1.8(a)

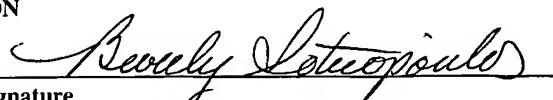
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Date: October 23, 2006

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- (1) a final action under Section 1.113,
- (2) a notice of allowance under Section 1.311, or
- (3) an action that otherwise closes prosecution in the application

whichever occurs first.

☐ Accompanying this transmittal is the fee set forth in 37 C.F.R. Section 1.17(p) for submission of an information disclosure statement under Section 1.97(c). (\$180.00).

☐ Each item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. 37 C.F.R. Section 1.97(e)(1).

☐ No item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application and to the knowledge of the person signing the statement after making reasonable inquiry, was known to any individual designated in Section 1.56(c) more than three months prior to the filing of the information disclosure statement. 37 C.F.R. Section 1.97(e)(2).

OR

☐ The information disclosure statement transmitted herewith is being filed *after* a final action under Section 1.113, or a notice of allowance under Section 1.311, whichever occurs first, but before, or simultaneously with, the payment of the issue fee.

☐ In accordance with the requirements of 37 C.F.R. Section 1.97(d):

A. ☐ Accompanying this transmittal is the fee set forth in 37 C.F.R. Section 1.17(p) for submission of an information disclosure statement under Section 1.97(c). (\$180.00):

B. ☐ Each item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. 37 C.F.R. Section 1.97(e)(1).

C. ☐ No item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application and to the knowledge of the person signing the statement after making reasonable inquiry, was known to any individual designated in Section 1.56(c) more than three months prior to the filing of the information disclosure statement. 37 C.F.R. Section 1.97(e)(2).

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FEE PAYMENT

3. ☐ The fee due is set forth in 37 C.F.R. Section 1.17(p) for submission of an information disclosure statement under Section 1.97(c) (\$180.00).

☒ Applicant believes no fee is due in connection with this submission.

		Fee due	\$0.00
METHOD OF PAYMENT OF FEE			
4. <input type="checkbox"/> Attached is a check in the amount of \$ _____.			
<input type="checkbox"/> Charge Account No. 501668 in the amount of		\$0.00	.

☐ A duplicate of this request is attached.

If any additional fees are due, please charge Account 501668.

<u>October 23, 2006</u>	MILLENNIUM PHARMACEUTICALS, INC. By <u>Tracy M. Sioussat</u> Tracy M. Sioussat, Ph.D. Registration No. 50,609 40 Landsdowne Street Cambridge, MA 02139 Telephone - 617-374-7679 Facsimile - 617-551-8820
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INFORMATION DISCLOSURE STATEMENT

List of Sections Forming Part of This Information Disclosure Statement

The following sections are being submitted for this Information Disclosure Statement:

1. ☒ Preliminary Statements
2. ☒ Form PTO/SB/08B (1 page)
3. ☒ Copy of Listed Information Item(s) Accompanying This Statement
4. ☒ Identification of Person(s) Making This Information Disclosure Statement

Section 1. Preliminary statements

Applicants submit herewith patents, publications or other information, of which they are aware that they believe may be material to the examination of this application, and in respect of which, there may be a duty

CERTIFICATION UNDER 37 C.F.R. SECTIONS 1.8(a) and 1.10*

I hereby certify that, on the date shown below, this correspondence is being:

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to disclose.

The filing of this information disclosure statement shall not be construed as a representation that a search has been made (37 C.F.R. section 1.97(g)), an admission that the information cited is, or is considered to be, material to patentability, or that no other material information exists.

The filing of this information disclosure statement shall not be construed as an admission against interest in any manner. Notice of January 9, 1992, 1135 O.G. 13-25, at 25.

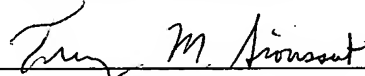
Section 2. Copies of Listed Information Items Accompanying This Statement

Legible copies of all relevant portions of items listed in Form PTO/SB/08B (substitute for Form PTO-1449) (references C1-C9) accompany this information statement.

October 23, 2006

MILLENNIUM PHARMACEUTICALS, INC.

By



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Substitute for form 1449B/PTO		Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>		Application Number	10/728,055
		Filing Date	December 4, 2003
		First Named Inventor	George Mulligan
		Group Art Unit	1642
		Examiner Name	Reddig, Peter J.
Attorney Docket Number	MPI02-202P1RNM		
OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No.¹	Include the name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and-or country where published.	T²
	C1	Adams, Julian, et al., "Proteasome Inhibitors: A Novel Class of Potent and Effective Antitumor Agents," <i>Cancer Research</i> , Vol 59 (June 1, 1999) pp 2615-2622	
	C2	Adams, Julian, "Development of the Proteasome Inhibitor PS-341," <i>The Oncologist</i> , Vol. 7 (2002) pp 9-16	
	C3	Lightcap, Eric S., et al., "Proteasome Inhibition Measurements: Clinical Application," <i>Clinical Chemistry</i> , Vol. 46, No. 5 (2000) pp 673-683	
	C4	Hochwald, Steven N., et al., "Antineoplastic Therapy in Colorectal Cancer through Proteasome Inhibition," <i>The American Surgeon</i> , Vol. 69 (January 2003) pp 15-23	
	C5	Richardson, Paul G., et al., "A Phase 2 Study of Bortezomib in Relapsed, Refractory Myeloma," <i>The New England Journal of Medicine</i> , Vol. 348, No. 26 (June 26, 2003) pp 2609-2617	
	C6	van de Vijver, Marc J., et al., "A Gene-Expression Signature as a Predictor of Survival in Breast Cancer," <i>The New England Journal of Medicine</i> , Vol. 347, No. 25 (Dec. 19, 2002) pp 1999-2009	
	C7	Barden, Catherine B., et al., "Classification of Follicular Thyroid Tumors by Molecular Signature: Results of Gene Profiling," <i>Clinical Cancer Research</i> , Vol. 9 (May 2003) pp 1792-1800	
	C8	Jiang, Xiaoyan, et al., "Ahi-1, a Novel Gene Encoding a Modular Protein with WD-40-Repeat and SH3 Domains, Is Targeted by the Ahi-1 and Mis-2 Provirus Integrations," <i>Journal of Virology</i> , Vol. 76, No. 18 (Sept. 2002) pp 9046-9059	
	C9	Jiang, Xiaoyan, et al., "Deregulated Expression in Ph+ Human Leukemias of AHI-1, a Gene Activated by Insertional Mutagenesis in Mouse Models of Leukemia," <i>Blood</i> , Vol. 103, No. 10 (May 15, 2004) pp 3897-3904	
Examiner Signature			Date Considered

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Unique citation design number. ²Applicant is to place a check mark here if English language Translation is attached.

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